K003276

NuMED, Inc.
P.O. Box 129
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Contact Nichelle LaFlesh, Regulatory Affairs Mgr.

DEC - 1 2000

Date 19 September 2000

510(k)

SUMMARY

For The NuMED, Inc.

Tyshak Mini Pediatric PTV Catheter

SECTION SIX: 510(K) Summary

A. Trade Name: NuMED, Inc Tyshak Mini Pediatric PTV Catheter

B. Common Name: PTV Catheter

C. Device Class: II, 74MAD; 21 CFR 870.1250

D. Predicate Devices: Tyshak PTV Catheters

E. Description - The NuMED, Inc. Tyshak Mini Pediatric PTV catheter is a coaxial catheter for use in PTV applications where a small introduction site is necessary. The catheters inner and outer shafts are constructed of polymeric tubing. The catheter features a molded proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon made of polymeric material. This balloon is of the non-compliant variety. This balloon is designed to insert through the smallest possible introduction sleeve. The distal lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. This lumen has radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. The catheter is blue in color and the balloon material is clear. The catheter balloon diameter is stamped onto the Y connector and the inflation extension is labeled with balloon diameter x balloon length x introducer size x shaft size x usable length x guidewire size and the catheter lot number. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches. This catheter is very similar in construction to the Tyshak PTV catheters except for the smaller guidewire and shaft size. The Tyshak Mini catheter is available in standard diameters from **4mm** to **10mm.** The lengths available will be **2cm** for the **4mm – 8mm**, and **2 and 4cm** for the **9mm – 10mm.** The Guidewire size will be **0.014",** and the shaft size will be **2.5Fr** for the **4mm – 8mm** and **3.5Fr** for the **9mm and 10mm**.

F. Indication – This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications. A patient with isolated pulmonary stenosis. A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2000

Ms. Nichelle R. LaFlesh
Regulatory Affairs Manager
NuMED, Inc.
P.O. Box 129
Nicholville, NY 12965

Re: K003276
Trade Name: NuMED, Inc. Tyshak Mini Pediatric PTV Catheter
Regulatory Class: II (two)
Product Code: 74 LIT, 74 DQY
Dated: November 8, 2000
Received: November 9, 2000

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **NuMED, Inc. Tyshak Mini**

Pediatric PTV Catheter

Indications For Use:

This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications.

- A patient with isolated pulmonary stenosis.
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003276

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)